

## REMARKS

### Status of the Claims.

Claims 1-43 and 78 are pending with entry of this amendment, no claims being cancelled and no claims being added herein. Claims 6-10, 17-21, 24-29, 36-40, and 77 are amended herein. These amendments introduce no new matter. These claims are amended simply to correct the reference from "nucleotides" to "--amino acids'--". These amendments do not change the scope of the claimed invention.

### Election/Restriction.

Applicants understand the restriction requirement to be made final. Applicants further understand that claims 2, 4, 5, 13-16, and 31-35 are withdrawn from further consideration as being drawn to a nonelected species there allegedly being no allowable generic or linking claim.

Applicants further understand, however, that claim 1, for example, is a generic and linking claim and upon an indication of allowability of claim 1 with respect to the species presently under examination, the remaining species will properly be examined.

### 35 U.S.C. §112, Second Paragraph.

Claims 6-12, 17-30, 36-43, and 78 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite of the recitation of "nucleotides". These claims are amended herein to recite "amino acids" thereby obviating this rejection.

### 35 U.S.C. §112, first paragraph.

Claims 1, 3, 6-12, 17-30, 36-43, and 78 were rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabled. In particular the Examiner alleged that the specification does not provide a repeatable method of obtaining the monoclonal antibody clone C25 and required a deposit. Applicants traverse.

Claim 1, for example is directed to:

1 An isolated single-chain antibody that specifically binds to an epitope specifically bound by an antibody expressed by a clone selected from the group consisting of clone S25, clone C25, clone C39, clone 1C6, and clone 1F3, wherein said antibody binds to and neutralizes botulinum neurotoxin type A (BoNT/A). [emphasis added]

While claim 3, for example recited

3. The antibody of claim 1, wherein said clone is C25 or C39.

The claims are thus not drawn to the clones, but rather to antibodies expressed by the clones or antibodies that cross-react with epitopes bound by antibodies expressed by the clones.

The amino acid sequences of the reference antibodies (*e.g.* C25) are expressly provided in Table 4. Thus, for example the amino acid sequence of the antibody expressed by C25 is item 13 in Table 4. Using the provided amino acid sequence, one of skill can readily prepare a vector that expresses such a sequence. Thus, the antibody expressed by C25 (or the other clones) can readily be produced using routine recombinant DNA methodology and, accordingly, no deposit is required to enable the presently claimed invention. In view of this the rejection of claims 1, 3, 6-12, 17-30, 36-43, and 78 under 35 U.S.C. §112, first paragraph, should be withdrawn.

**35 U.S.C. §102.**

**Amersdorder *et al.***

Claims 1, 3, 6-12, 17-30, 36-43 and 78 were rejected under 35 U.S.C. §102(a) as allegedly anticipated by Amersdorfer *et al.* (1997) *Infect. Immun.*, 65(9): 3743-3752. Upon an indication of withdrawal of the rejection under 35 U.S.C. §102 in light of Chen *et al.* (*infra*) and the rejection under 35 U.S.C. §112, Applicants will provide a Katz Declaration obviating this rejection.

**Chen *et al.***

Claims 1, 3, 11, and 12 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Chen *et al.* (1997) *Infection and Immunity*, 65(5): 1626-1630. Applicants traverse.

The Examiner is respectfully reminded that anticipation requires that **all** of the limitations of a claim be found in the reference. *Kalman v Kimberly-Clark Corp.*, 218 USPQ 781, 789 (Fed. Cir. 1983).

In the instant case, the claims are directed to antibodies that bind to epitopes bound by the antibodies expressed by clones **S25, C25, C39, 1C6, or 1F3**, wherein the antibody is a neutralizing antibody. The Examiner has failed to identify any teaching in Chen *et al.* establishing that the antibodies recited therein bind to epitopes bound by the present claimed antibodies. In addition, Chen

*et al.* offers no teaching that any of the antibodies recited therein are neutralizing. In view of this, Chen *et al.* fails to meet all of the limitations of the presently pending claims. The Examiner has failed to make his *prima facie* case and the rejection under 35 U.S.C. §102(b) should be withdrawn.

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3513.

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Respectfully submitted,



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